ChymoCorp

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February 8, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

Dear Sir/Madam:

ChymoCorp submits this petition pursuant to 21 C.F.R. 10.25(a) and 10.30 and in accordance with the regulations at 21 C.F.R. 314.122 to request that the Commissioner of the Food and Drug Administration ("Commissioner") make a determination that a drug listed in the Discontinued Drug Products section of the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") has not been voluntarily withdrawn from marketing for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner make a determination that Abbott Laboratories' Chymopapain (Chymodiactin), have not been voluntarily withdrawn or withheld from sale from safety or effectiveness reasons and that an Abbreviated New Drug Application ("ANDA") may be submitted and approved pursuant to 21 C.F.R. 314.122 and 314.161 using Chymopapain as the Reference Listed Drug ("RLD"). If appropriate, an application may be made under the Orphan Drug Act (as amended) 526(360bb)(a)(1) and appropriate sections.

B. Statement of Grounds

The Orange Book is a list of all drug products approved by the Food and Drug Administration ("FDA") which are eligible for submission as ANDAs. The August 1999 Supplement to the 1999 Orange Book (19th edition) lists Chymopapain showing "non-marketed status". Prior to a 1984 law, FDA did not include in the Orange Book any product not on the market. However, since the enactment of the 1984 law, any approved drug, whether it is on the market or not, is still included in the Orange Book and is still a listed drug. Pursuant to 21 C.F.R. 314.161(a)(I),

FDA must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA using the listed drug as a RLD may be approved.

Chymopapain is currently listed in the Orange Book under Discontinued Drug Products and is not available for sale in the marketplace. ChymoCorp intends to use Chymopapain as it RLD in submitting an ANDA for Chymopapain. Because there is not current commercial distribution of Chymopapain, and as such there is no product in the marketplace against which ChymoCorp may conduct the bioequivalence trial, 21 C.F.R. 314.94(a)(7), or any currently approved labeling ChymoCorp may use in a side-by-side comparison, 21 C. F.R. 314.94 (a)(8), for its proposed ANDA, ChymoCorp requests that FDA determine whether Abbott Laboratories' decision not to market Chymopapain for reasons of safety or effectiveness. As such, ChymoCorp is submitting this petition pursuant to 21 C.F.R. 314.161(a)(3). Consistent with 21 C.F.R. 314.122(a) and 314.161(b), ChymoCorp has no information or evidence available to it concerning the reason that Chymopapain is not available for sale. However, since FDA approved Chymopapain as safe and effective since 1982, we submit that the non-marketing of Chymopapain may well be strictly an economic/strategic decision by Abbott Laboratories and is totally unrelated to safety or efficacy.

C. Environmental Impact

An environmental assessment on the action requested in this petition qualifies for a categorical exclusion under 21 C.F.R. 25.31. Therefore, an environmental assessment is not required for the requested action.

D. Economic Impact

Pursuant to 21 C.F.R. 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. ChymoCorp will promptly provide such information if so requested.

E. Certification

ChymoCorp certifies that, to the best of its knowledge an belief, this petition includes all information and views on which the petition review, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,

James W. Simmons, Jr.
President

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